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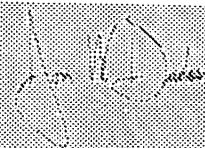
October 28, 2004

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FILING DATE: September 23, 2003
RELATED PCT APPLICATION NUMBER: PCT/US04/31202

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Jon W Dudas

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(e).

Express Mail Label No. EV308811674US

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Additional Inventors are being named on the _____ separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)

RAPID TEST FOR GLYCATED ALBUMIN

DIRECT ALL CORRESPONDENCE TO:

CORRESPONDENCE ADDRESS

☐ Customer Number

31278

OR

TYPE CUSTOMER NUMBER HERE

☒ Firm or
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ENCLOSED APPLICATION PARTS (check all that apply)

☒ Specification Number of pages: 11

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☒ Other (specify): 2 pgs claims; 1 pg abstract

☐ Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL PATENT APPLICATION (check one)

☒ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check or money order is enclosed to cover the filing fees

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(Page 1 of 1)

Respectfully submitted,

SIGNATURE

DATE: 9/23/03

REGISTRATION NO. 39,645

(if appropriate)

DOCKET NUMBER: 14149.0001

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing and submitting the completed application to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, US Patent and Trademark Office, US Department of Commerce, P. O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES LETTERS PATENT

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CERTIFICATE OF MAILING

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Trudi Thompson

RAPID TEST FOR GLYCATED ALBUMIN

BACKGROUND OF THE INVENTION

[0001] Diabetes mellitus or diabetes is a disease characterized by elevated levels of plasma glucose. Uncontrolled hyperglycemia is associated with increased risk of vascular disease including, nephropathy, neuropathy, retinopathy, hypertension, and death. There are two major forms of diabetes. Type 1 diabetes (or insulin-dependent diabetes) and Type 2 diabetes (or noninsulin-dependent diabetes). The American Diabetes Association has estimated that approximately 6% of the world population has diabetes.

[0002] The goal of diabetic therapy is to maintain a normal level of glucose in the blood. The American Diabetic Association has recommended that diabetics monitor their blood glucose level at least three times a day in order to adjust their insulin dosages and/or their eating habits and exercise regimen. However, glucose tests can only measure a point in time result and does not provide an overall assessment of glycemic control over a period of time. The measurement of glycated albumin has proven to be valuable measure of the effectiveness of glycemic control over the preceding 2-3 weeks. The basis for measuring glycated albumin depends on the nonenzymatic glycosylation of albumin and is directly proportional to the level of glucose in plasma over a period of time. The half-life of albumin in plasma is 2-3 weeks and as glycosylation occurs at a constant rate over time the level of glycated albumin provides a measure of the average blood glucose level over the preceding two to three weeks.

[0003] Frequent monitoring of the individuals glycated albumin would provide an accurate assessment of overall effectiveness of glycemic control in the individual.

[0004] Current methodology for performing tests for glycated albumin are complex to perform or require expensive instrumentation and are generally performed in laboratories.

[0005] It would be advantageous to develop a simplified point-of-care assay that could be utilized in a doctor's office or by the patient and there is intensive research to develop such a test.

[0006] The present invention describes a simplified point-of-care assay that utilizes disposable test strips and a reusable measuring instrument.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Figure 1 depicts a first view of the test strips made in accordance with the teachings of the present invention.

[0008] Figure 2 depicts a second view of the test strips made in accordance with the teachings of the present invention.

[0009] Figure 3 depicts a side view of the test strips made in accordance with the teachings of the present invention.

[0010] Figure 4 depicts a reflectance spectrometer as used with the test strips made in accordance with the methods of the present invention.

[0011] Figure 4b depicts a fluorometer as used with the test strips made in accordance with the methods of the present invention.

[0012] Figure 5 depicts a first view of a test strip cassette made in accordance with the teachings of the present invention.

[0013] Figure 6 depicts a second view of a test strip cassette made in accordance with the teachings of the present invention.

[0014] Figure 7 depicts a reflectance spectrometer and test strip as used in accordance with the methods of the present invention.

DESCRIPTION OF THE INVENTION

[0015] This invention utilizes the principle of lateral flow immunochromatography to measure both glycated albumin and total albumin. The patient's blood sample is placed in a test cassette that contains reagents to separate the plasma from the red blood cells and to perform the test. The test cassette is then inserted into a measuring instrument that reads, calculates and reports the result.

Principle

[0016] The Rapid Assay for glycated albumin is an immunochromatographic method that utilizes antibodies to glycated albumin and antibodies to total albumin on test strips. In order to measure the percent of glycated albumin to total albumin two procedures are involved. The first procedure utilizes an immunochromatographic test strip to measure glycated albumin. The second procedure utilizes an immunochromatographic test strip

to measure total albumin. Both strips are contained within a single exterior cassette (Figure 1) that is inserted into a measuring instrument (Figure 7) that automatically reads, calculates and displays the result.

1. Glycated Albumin Test

[0017] The test strip for measuring glycated albumin is shown in Figures 1 and 2. It consists of a cellulose nitrate membrane (1) or similar membrane support, to which antibody to glycated albumin has been fixed as a band (2). There is a sample application pad (3) that contacts a conjugate pad (4) containing microparticles coated with anti-glycated albumin antibody. There is a control band to bind excess unreacted microparticles (5) and a reservoir pad (6) at the distal end of the membrane to absorb excess sample fluid. The test strip is enclosed within a rigid cassette containing a sample well and window segments to allow for visualization and measurement of the test result.

[0018] To perform the test a small volume of blood is placed into the sample well. The blood will migrate into the sample application pad which filters and binds the red blood cells allowing the plasma to pass through into the conjugate pad where it will react with the antibody coated microparticles. Any glycated albumin present will bind to the anti-glycated albumin antibody coated microparticles. The microparticles will continue to migrate across the cellulose membrane until they come into contact with the fixed band of anti-glycated albumin antibody. Any glycated albumin bound to microparticles will become bound to the membrane and will cause the bound microparticles to form a visible band. The intensity of the band will be proportional to the amount of glycated albumin that was bound to the microparticles. The intensity of the visible band may be estimated visually by comparison to a visual standard or measured in an instrument developed for this purpose.

2. Total Albumin Test

[0019] The test strip for measuring total albumin is shown in Figures 1 and 2. It consists of a cellulose nitrate membrane (1) or similar membrane to which antibody to albumin has been fixed as a band (7). There is a sample application pad (3) that

contacts a conjugate pad (8) containing microparticles coated with anti-albumin antibody. There is a control band (9) to bind excess unreacted microparticles and a reservoir pad (6) at the distal end of the membrane to absorb excess sample fluid. The test strip is enclosed within a rigid cassette containing a sample well and window segments to allow for visualization and measurement of the test result.

[0020] To perform the test a small volume of blood is placed into the sample well. The blood will migrate from the sample application pad which will filter and bind the red blood cells allowing the plasma to pass into the conjugate pad where it will react with the antibody coated microparticles. Any albumin present will bind to the anti-albumin antibody coated microparticles. The microparticles will continue to migrate across the cellulose membrane until they come into contact with the fixed band of anti-albumin antibody. Any albumin bound to microparticles will become bound to the membrane and will cause the bound microparticles to form a visible band. The intensity of the band will be proportional to the amount of albumin that was bound to the microparticles. The intensity of the visible band may be estimated visually by comparison to a visual standard or measured in an instrument developed for this purpose.

3. Measuring Instrument.

[0021] In the preferred embodiment of this invention the measuring instrument is a reflectance spectrophotometer that is specifically designed to measure the intensity of the glycated albumin test band on the glycated albumin test strip, and the total albumin test band on the total albumin test strip, and to calculate a result from these readings. The instrument has two sets of detectors, one detector set is for measuring glycated albumin and the other detector set is for measuring total albumin. The result is then calculated according to a mathematical algorithm derived from data obtained from measurement of standards of glycated and total albumin. The result is expressed as the percent of glycated albumin compared to total albumin present.

[0022] Alternatively, other methods for measuring the density of the aggregated microparticles may be employed. For example, the measuring instrument may be a fluorometer that measures the fluorescence that is emitted from microparticles that have been colored with a fluorescent dye such a fluorescein or rhodamine red. In this

example there will be an excitation beam of light projected onto the test bands and onto the control bands, and the emitted light from each band will be individually read by the corresponding detectors sensitive to the wavelength of the emitted light. The data reduction and reporting of the result will be as before.

Details of the Glycated Albumin Test: Description of the components and test procedure.

[0023] Blood sample such as that obtained from a finger stick is placed in the sample well and allowed to absorb into the sample application pad. The sample application pad is composed of porous cellulose material but other woven or porous materials such as glass fibers may be used. The materials can be purchased from many commercial suppliers (Millipore, Whatman, etc.). The sample application has a porosity that will not allow the passage of red blood cells but will allow the passage of the plasma. The application pad may be treated with binding agents such as lectins that will bind the red blood cells and prevent them from passage through the application membrane.

[0024] The filtered plasma sample then flows into a conjugate pad containing microparticles. The conjugate pad is composed of porous cellulose material but other woven or porous materials such as glass fibers may be used. The materials can be purchased from many commercial suppliers (Millipore, Whatman, etc.). The microparticles are composed of either colloidal gold or latex particles or acrylic particles or polystyrene particles with diameters that may range from 5-50 nm. These are available from commercial suppliers (Sigma, Chemicon, etc.). Microparticles composed of other materials may also be employed and are within the scope of this invention. Colored or fluorescent dyed microparticles may be employed to increase the sensitivity of measurement of the result.

[0025] The microparticles are coated with antibody to glycated albumin. The anti-glycated albumin antibodies are prepared in immunized animals such as rabbits, sheep, goats, or other immunized species of animals, or by monoclonal antibody techniques. Either the whole antiserum, or the IgG purified fraction, or the affinity purified antibody to glycated albumin may be employed. The methods for immunization of animals and the

preparation and purification of antibody is performed according to standard laboratory procedures and known to those skilled in the art.

[0026] Similarly, the methods of developing monoclonal antibody is performed according to standard laboratory procedures and known to those skilled in the art. The microparticles may be coated with the antibody by passive adsorption, or by chemical conjugation such as covalent binding, or through binding to an intermediate agent such as to Protein A-coated microparticles. The methods for coating microparticles are performed according to standard laboratory procedures and are familiar to those skilled in the art.

[0027] When the test sample comes into contact with the antibody coated microparticles the antibody will bind any glyated albumin present. The microparticles will continue to migrate across the membrane until they reach the band of anti-glyated albumin antibody fixed to the membrane. Any microparticles containing bound glyated albumin will become bound to the fixed band of anti-glyated albumin antibody to form a visible band.

[0028] Alternatively the membrane may be treated with chemicals known to bind glyated proteins such as phenyl boronic acids and applied as a band to the membrane strip. Any microparticles containing bound glyated albumin will become bound to the fixed band of phenyl boronic acid to form a visible band. In either case the density of the band formed will be directly proportional to the amount of glyated albumin present in the blood sample. The density of the band can be measured using a reflectance spectrometer for colored microparticles or a fluorometer for microparticles dyed with a fluorescent compound. The measurements are used to calculate the percentage of glyated albumin compared to total albumin in the blood sample.

Internal Controls:

[0029] In order to verify that the test strips are functioning correctly each test strip may have an additional band of fixed reagent located distal to the test band. For the glyated albumin test strip this control band is composed of antibody directed against the species antibody that was used to coat the microparticles. For example, if rabbit anti-human glyated albumin antibody was used to coat the microparticles then the control band would use another species such as goat or sheep antibodies directed

against rabbit IgG immunoglobulin. The antibodies in the control band will bind to the excess unreacted antibody coated microparticles that were not bound to the test band but continued to migrate across the membrane until bound by the control reagent. The intensity of the control band is measured using a reflectance spectrometer or fluorometer and utilizing the data to calculate if the test is performing correctly.

Details of the Total Albumin Test : Description of the components and test procedure.

[0030] Blood sample such as that obtained from a finger stick is placed in the sample well and allowed to absorb into the sample application pad. The sample application pad is composed of porous cellulose material but other woven or porous materials such as glass fibers may be used. The materials can be purchased from many commercial suppliers (Millipore, Whatman, etc.). The sample application has a porosity that will not allow the passage of red blood cells but will allow the passage of the plasma. The application pad may be treated with binding agents such as lectins that will bind the red blood cells and prevent them from passage through the application membrane.

[0031] The filtered plasma sample then flows into a conjugate pad containing microparticles. The conjugate pad is composed of porous cellulose material but other woven or porous materials such as glass fibers may be used. The materials can be purchased from many commercial suppliers (Millipore, Whatman, etc.). The microparticles are composed of either colloidal gold or latex particles or acrylic particles or polystyrene particles with diameters that may range from 5-50 nm. These are available from commercial suppliers (Sigma, Chemicon, etc.). Microparticles composed of other materials may also be employed and are within the scope of this invention. Colored or fluorescen dyed microparticles may be employed to increase the sensitivity of measurement of the result.

[0032] The microparticles are coated with antibody to albumin. The anti-albumin antibodies are prepared in immunized animals such as rabbits, sheep, goats, or other immunized species of animals, or by monoclonal antibody techniques. Either the whole antiserum, or the IgG purified fraction, or the affinity purified antibody to albumin may be employed. The methods for immunization of animals and the preparation and purification of antibody is performed according to standard laboratory procedures and

known to those skilled in the art. Similarly, the methods of developing monoclonal antibody is performed according to standard laboratory procedures and known to those skilled in the art.

[0033] The microparticles may be coated with the antibody by passive adsorption, or by chemical conjugation such as covalent binding, or through binding to an intermediate agent such as to Protein A-coated microparticles. The methods for coating microparticles are performed according to standard laboratory procedures and are familiar to those skilled in the art.

[0034] When the test sample comes into contact with the antibody coated microparticles the antibody will bind any albumin present. The microparticles will continue to migrate across the membrane until they reach the band of anti- albumin antibody fixed to the membrane. Any microparticles containing bound albumin will become bound to the fixed band of anti-albumin antibody to form a visible band. The density of the band formed will be directly proportional to the amount of albumin present in the blood sample. The density of the band can be measured using a reflectance spectrometer for colored microparticles or a fluorometer for microparticles dyed with a fluorescent compound. The measurements are used to calculate the percentage of glycated albumin compared to total albumin in the blood sample.

Internal Controls:

[0035] In order to verify that the test strips are functioning correctly each test strip will have an additional band of fixed reagent located distal to the test band. For the test strip this control band is composed of antibody directed against the species antibody that was used to coat the microparticles. For example, if rabbit anti-human albumin antibody was used to coat the microparticles then the control band would use another species such as goat or sheep antibodies directed against rabbit IgG immunoglobulin. The antibodies in the control band will bind to the excess unreacted antibody coated microparticles that were not bound to the test band but continued to migrate across the membrane until bound by the control reagent. The intensity of the control band is measured using a reflectance spectrometer or fluorometer and utilizing the data to calculate if the test is performing correctly.

Details of the Measuring Instrument.

[0036] The measuring instrument shown in Figure 4a is a reflectance spectrometer and is composed of the following components: A detector (10) calibrated to read the reflectance of the microparticles fixed to the glycosylated albumin band on the glycosylated albumin test strip; a detector (11) calibrated to read the reflectance of the microparticles fixed to the control band on the glycosylated albumin test strip; a detector (12) calibrated to read the reflectance of the microparticles fixed to the total albumin band on the total albumin test strip; a detector (13) calibrated to read the reflectance of the microparticles fixed to the control band on the total albumin test strip; a computing chip and electronic circuitry (14) to collect the data from the detectors and to calculate the result.

[0037] The calculations are based on a mathematical algorithm and a reference standard curve. The standard curve is derived from value assigned standards and the instrument is precalibrated at the manufacturing facility before it is distributed. The result is expressed as the percent of glycosylated albumin compared to total albumin and displayed on a liquid crystal display (15). Successive results obtained over a period of time are stored in the instrument and can be retrieved on demand and displayed in numerical format or in graphical format. Typically, the result will be displayed along with the date of the test. The user may then select to have all the previous stored test results and their date displayed, or have all the results presented as a graph so that any trends can be identified. In order to enter commands to the internal computer the instrument may contain either buttons or a keyboard on its exterior case.

[0038] The results can also be downloaded via an external port to an external computer and/or printed on an external printer (16). The instrument's electronics are powered by an internal battery (17) and/or external power source (18). The components are housed in a rigid exterior case (19) with a window (20) for the display monitor and an aperture (21) for inserting the test cassette.

[0039] Alternatively, the measuring instrument may be a fluorometer (Figure 4 b) that measures the density of aggregated microparticles that have been colored with a fluorescent dye such as fluorescein or rhodamine. The fluorometer is composed of the following components: A detector (22) calibrated to read the fluorescence of the

microparticles fixed to the glycated albumin band on the glycated albumin test strip; a detector (23) calibrated to read the fluorescence of the microparticles fixed to the control band on the glycated albumin test strip; a detector (24) calibrated to read the fluorescence of the microparticles fixed to the total albumin band on the total albumin test strip; a detector (25) calibrated to read the fluorescence of the microparticles fixed to the control band on the total albumin test strip; a computing chip and electronic circuitry (26) to collect the data from the detectors and to calculate the result. Using fluorescein dyed microparticles as an example, the excitation beam of light (492 nm wavelength) is projected onto the test bands and onto the control bands, and the emitted light from each band is individually read by the corresponding detectors sensitive to the wavelength (518 nm) of the emitted light. Alternatively, other fluorescent compounds may be used and the wavelength of the exciting beam and the wavelength of the resulting fluorescence which will be measured is adjusted accordingly.

[0040] The calculations are based on a mathematical algorithm and a reference standard curve. The standard curve is derived from value assigned standards and the instrument is precalibrated at the manufacturing facility before it is distributed. The result is expressed as the percent of glycated albumin compared to total albumin and displayed on a liquid crystal display (27). Successive results obtained over a period of time are stored in the instrument and can be retrieved on demand and displayed in numerical format or in graphical format. Typically, the result will be displayed along with the date of the test. The user may then select to have all the previous stored test results and their date displayed, or have all the results presented as a graph so that any trends can be identified. In order to enter commands to the internal computer the instrument may contain either buttons or a keyboard on its exterior case.

[0041] The results can also be downloaded via an external port to an external computer and/or printed on an external printer (28). The instrument's electronics are powered by an internal battery (29) and/or external power source (30). The components are housed in a rigid exterior case (31) with a window (32) for the display monitor and an aperture (33) for inserting the test cassette.

Design Modifications

[0042] In the preferred embodiment of this invention the test cassette is designed to enclose two test strips arranged in a parallel fashion (Figure 1) and the sample application well is constructed so that the test sample fluid can migrate across both test strips simultaneously. However, other test cassette configurations may be employed using the same principles described in this invention and are considered to be within the scope of this invention. For example, the sample application well may be centrally located with the glycated albumin test strip and the total albumin test strip pointing outward in a radial direction. Figure 5 shows the test strips arrangement as diametrically opposite to each other and figure 6 shows the test strips to be at an angle to each other. In these examples the test cassette will be in the shape of a rectangular or square configuration. The aperture in the measuring instrument for inserting these cassettes will be adjusted to accommodate the shape of these cassettes.

[0043] In the preferred embodiment of this invention the measuring instrument is a reflectance spectrometer which measures a particular wavelength of the light reflected from the colored microparticles. The amount of reflected light measured at the test band and control band sites is directly proportional to the density of the aggregated microparticles at each site

[0044] Alternatively, a fluorometer may be used as the measuring instrument. In this example, the microparticles are colored with an internal fluorescent dye such as fluorescein or rhodamine red. The fluorescent dyed microparticles are excited at one wavelength of light which causes them to fluoresce at a different wavelength of light. The amount of fluorescence measured at the test band and control band sites is directly proportional to the density of the aggregated microparticles at each site.

[0045] In the preferred embodiment of this invention the measuring instrument would be of small size, compact and lightweight. In general, it would be similar in appearance and design to the various handheld glucometers in common usage. Such variations are cosmetic in nature and are considered to be within the scope of this invention.

What is claimed is:

1. An immunochromatographic procedure for measuring glycated albumin in a blood sample using a test strip that measures glycated albumin and a second test strip that measures total albumin. The measurements are performed using a reflectance spectrophotometer or fluorometer that reads, calculates and displays the result as the percentage of glycated albumin compared to total albumin in the sample.
2. According to claim 1 the procedure to measure glycated albumin consists of a test strip that utilizes microparticles coated with antibody to glycated albumin, and a second antibody to glycated albumin fixed to a membrane strip or phenyl boronic acid fixed to the membrane strip..
3. According to claims 1 and 2 the antibody to glycated albumin may be prepared in immunized animals or produced as a monoclonal antibody.
4. According to claims 1-3 the anti-glycated albumin antibody used may be the IgG purified fraction of the antiserum or the purified antibody itself.
5. According to claims 1 and 2 the microparticles used in the glycated albumin test strip may consist of colloidal gold particles or latex particles or polystyrene particles or acrylic particles or other solid phase microparticles. The size of said particles to be selected from a particle size range of from 5-50 nm in diameter.
6. According to claim 1 the procedure to measure total albumin consists of a test strip that utilizes microparticles coated with antibody to albumin, and a second antibody to albumin fixed to a membrane strip.
7. According to claim 1 and 6 the antibody to albumin may be prepared in immunized animals or produced as a monoclonal antibody.
8. According to claims 6 the anti-albumin antibody used may be the IgG purified fraction of the antiserum or the purified antibody itself.
9. According to claims 1 and 6 the microparticles used in the albumin test may consist of colloidal gold particles or latex particles or polystyrene particles or acrylic particles or other solid phase microparticles. The size of said particles to be selected from a particle size range of from 5-50 nm in diameter.
10. According to claims 5 and 9, in the preferred embodiment of this invention said microparticles to be selected from particle size diameters of either 10 nm, 20 nm,

30nm or 40 nm, or in increments within this range. The microparticles may be colored or dyed with a fluorescent compound in order to enhance the appearance of the bands and increase the sensitivity of the measurements.

11. According to claim 1 the glycated albumin test strip and the total albumin test strip may be arranged in parallel; or opposite to each other; or at an angle to each other. The test strips are enclosed in a rigid cassette whose shape will vary according to the arrangement of the internal test strips.

12. According to claim 1 the measuring instrument is a reflectance spectrometer composed of the following elements: a reflectance detector for measuring the glycated albumin test result and a reflectance detector for measuring the glycated albumin control band; a reflectance detector for measuring the total albumin test result and a reflectance detector for measuring the total albumin control band; an internal computer chip for measurement and calculation; a liquid crystal display; a external port to transfer data to an external computer and/or printer; a battery and/or an external power source; and a rigid external case with an aperture for inserting the test cassette.

13. According to claim 1 the measuring instrument is a fluorometer composed of the following elements: a fluorescence detector for measuring the glycated albumin test result and a fluorescence detector for measuring the glycated albumin control band; a fluorescence detector for measuring the total albumin test result and a fluorescence detector for measuring the total albumin control band; an internal computer chip for measurement and calculation; a liquid crystal display; a external port to transfer data to an external computer and/or printer; a battery and/or an external power source; and a rigid external case with an aperture for inserting the test cassette.

14. According to claims 12 and 13 the test results obtained from testing the same individual over a period of time are stored in the measuring instrument's computer memory. The stored data can be retrieved on demand and the results expressed in a numerical format or in a graphical format. The results can be displayed on the instrument's display monitor and/or transferred to an external computer or printer.

ABSTRACT

Patients with diabetes have elevated levels of glucose in their blood. The glucose can react with plasma albumin to form glycated albumin.. The amount of glycated albumin that is formed is directly correlated with the level of plasma glucose that the albumin has been exposed to over a period of time. The level of glycated albumin present in blood provides a measurement of the average level of glucose that was present in blood over the previous 2 to 3 week period.

This invention describes a rapid immunochromatographic assay for measuring both glycated albumin and total albumin. The test is performed using a cassette that contains the testing reagents and the results are measured in a reflectance spectrometer or fluorometer that automatically reads, calculates and displays the final result. The level of glycated albumin is expressed as a percentage of the total albumin present in blood. The results of tests that are performed over a period of time are stored in the instrument's memory and presented in a numerical or graphical format so that the individual's glycated albumin level can be monitored over time.

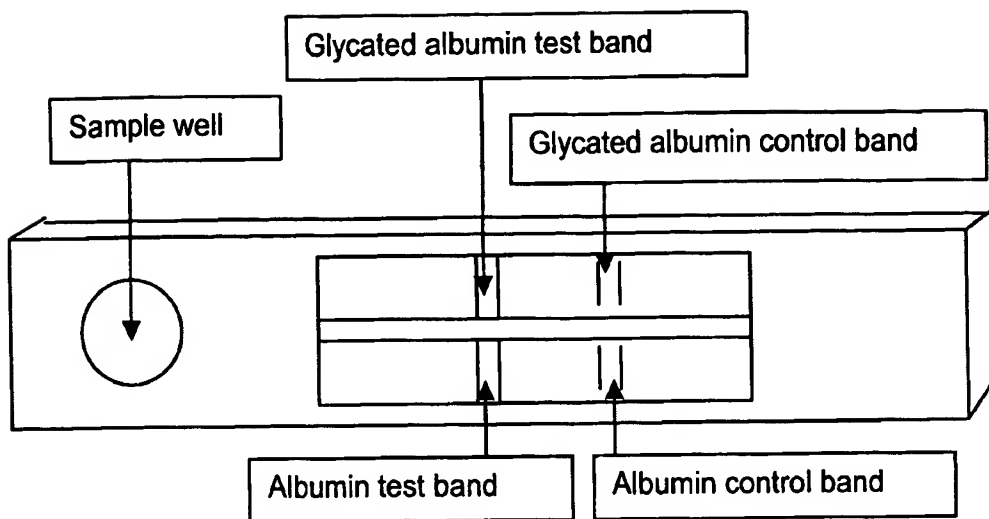


Figure 1. Test strips and cassette

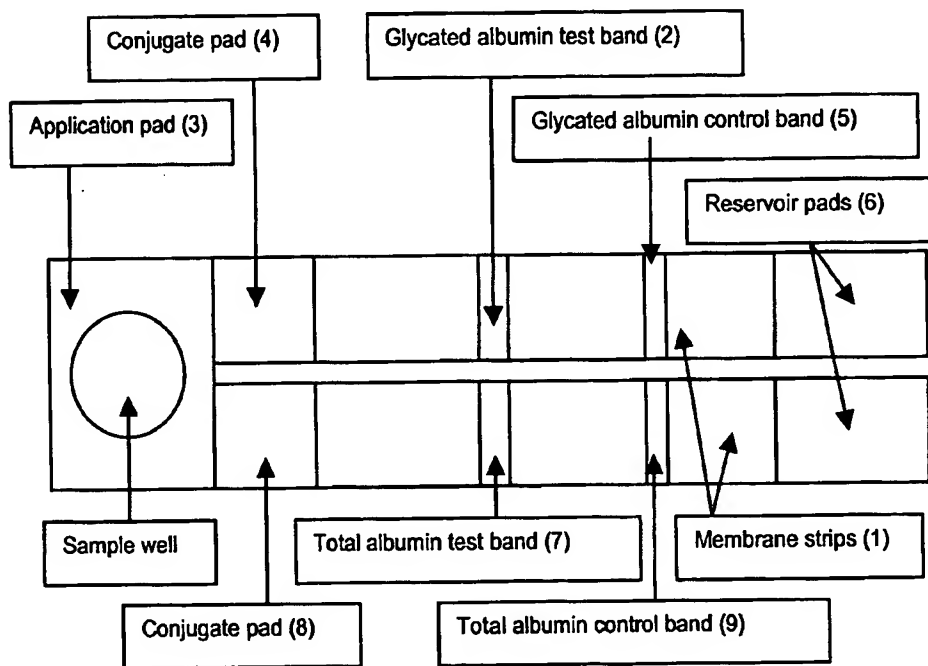


Figure 2 Test Strips: Overhead View

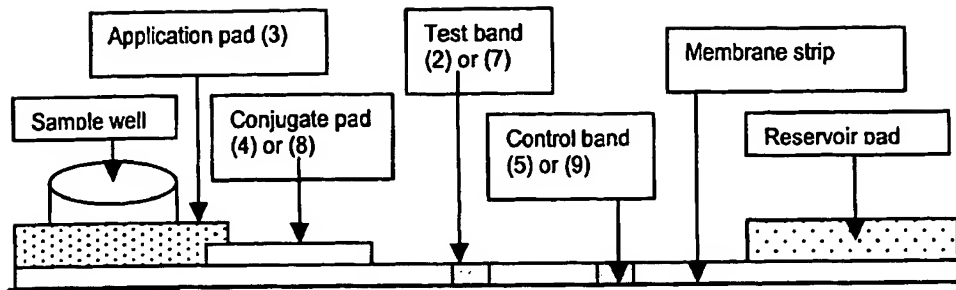


Figure 3 Test Strip. Side view

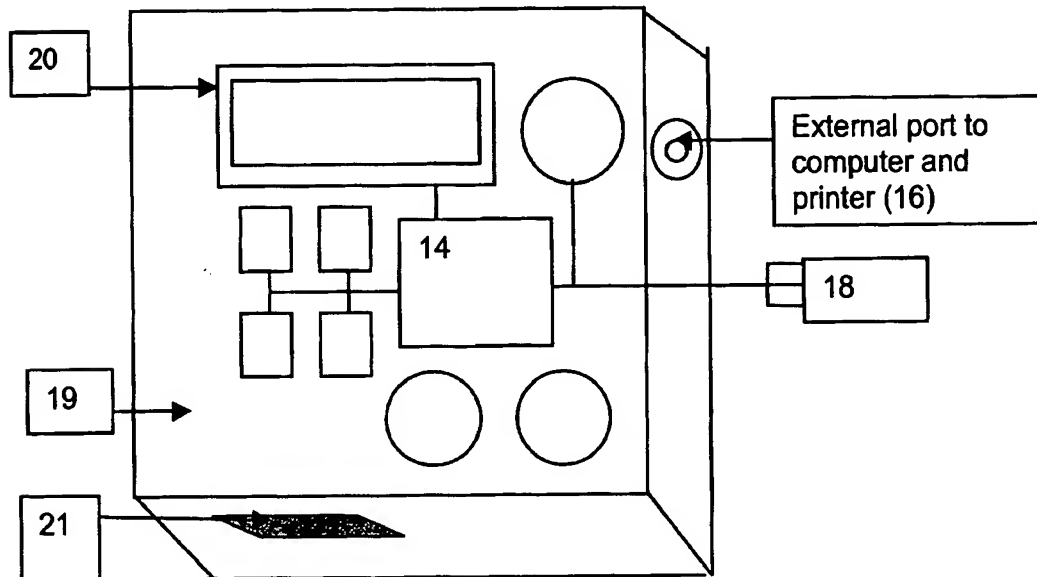


Figure.4. Reflectance Spectrometer

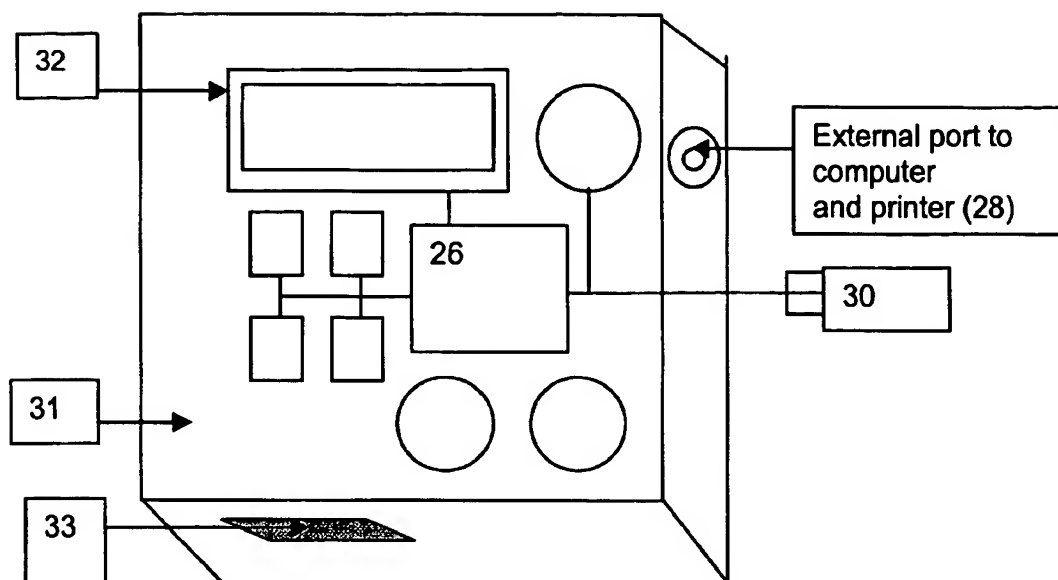


Figure.4b. Fluorometer

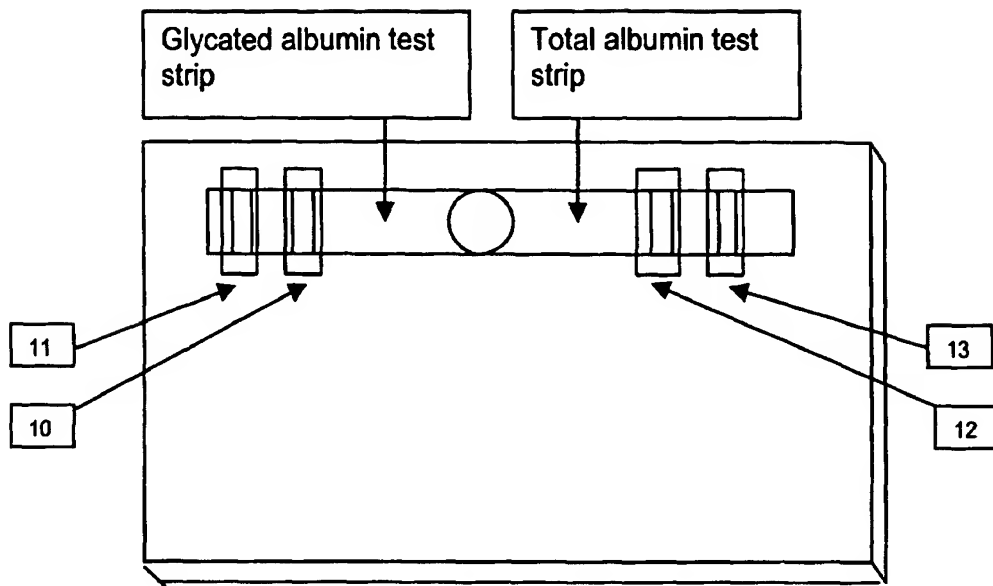


Figure 5. Modified strip arrangement and cassette design.

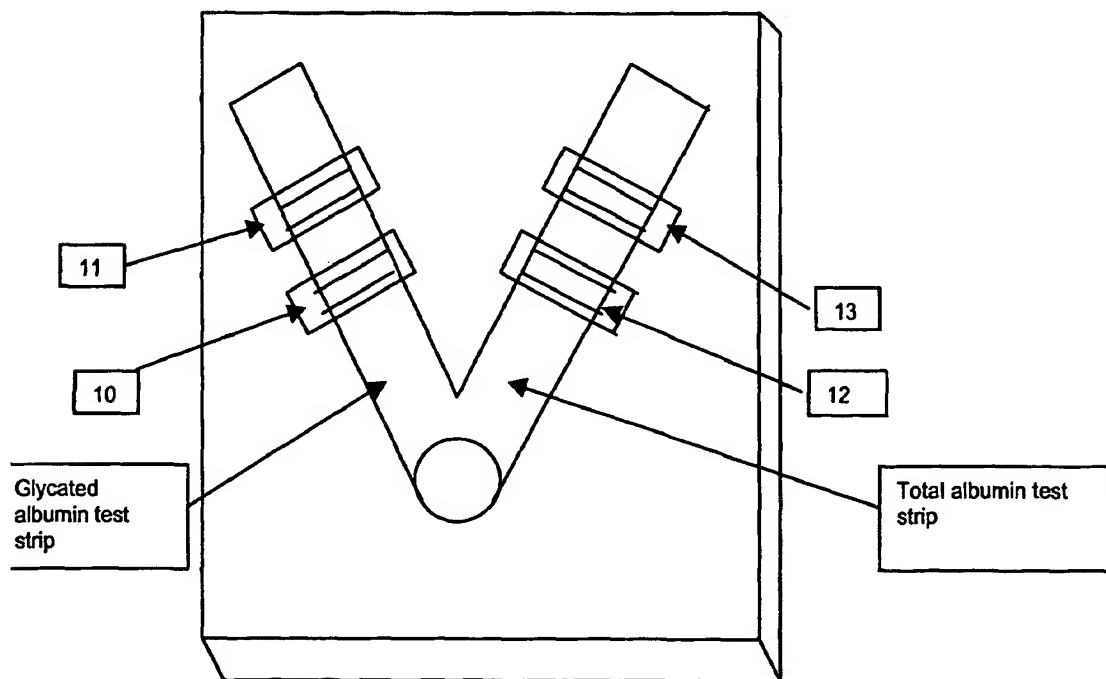


Figure 6. Modified strip arrangement and cassette design

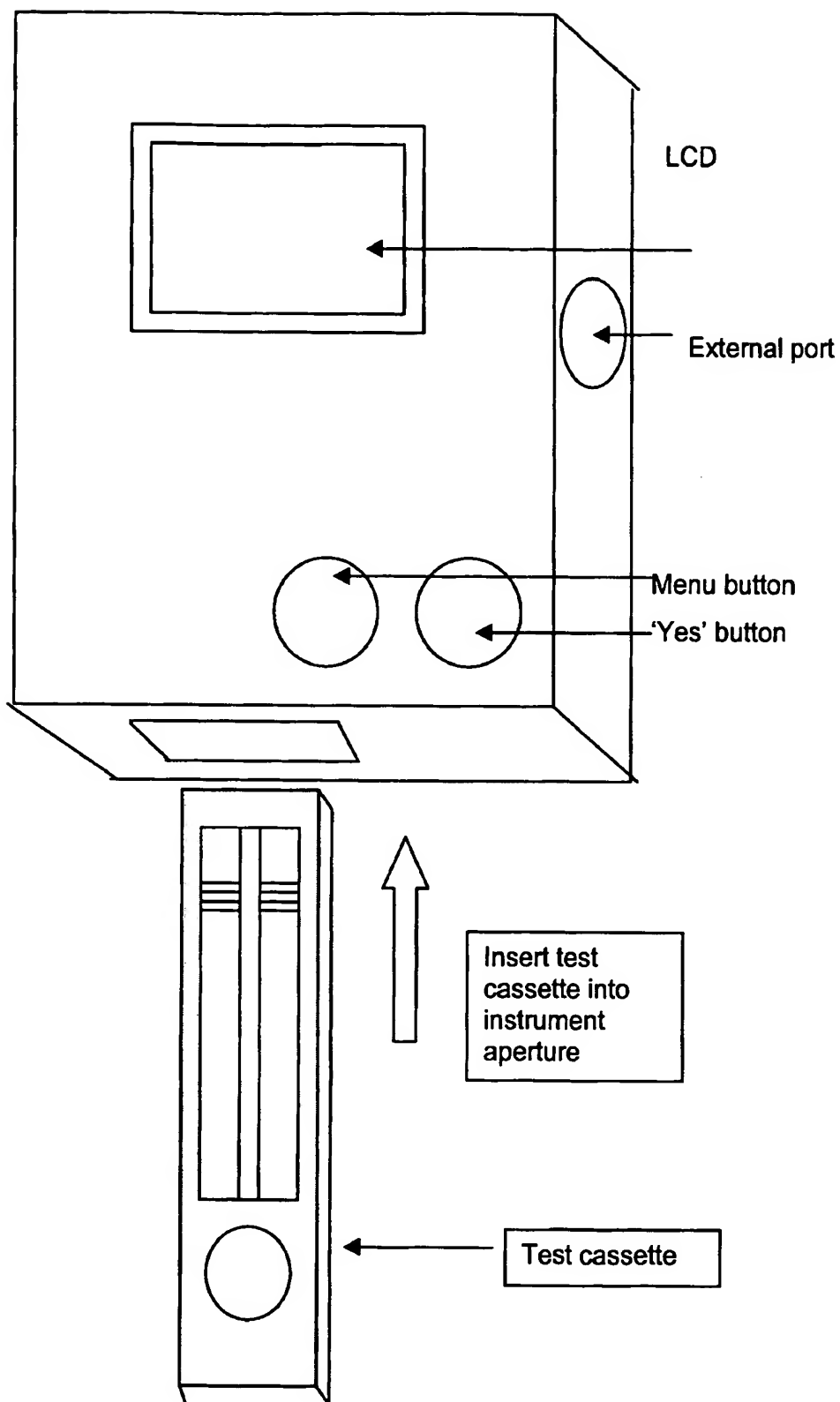


Figure 7. Spectrometer and Test Cassette

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